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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/636,052	KRAUSE ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-20* is/are pending in the application.

4a) Of the above claim(s) *3 and 17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Amendment filed 08/06/2009 is acknowledged. Claim 1 is amended. Claims 1,3-20 are pending. Claims 3,17-20 remain withdrawn from consideration. Claims 1, 4-16 are under examination.

Applicant's arguments have been fully considered and were deemed to be persuasive-in-part. Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 U.S.C. § 101 (non-statutory invention)

2. Rejection of claims 1, 4-16 under 35 U.S.C. 101 is withdrawn in view of amendments to the claims.

Claim Rejections - 35 USC § 103

Applicant's arguments with regard to art rejections of record are considered and deemed persuasive-in-part. The rejection over D'Urso et al. is withdrawn. The

rejection over Fleute et al. is revised as necessitated by amendment; consequently, applicant's arguments are moot in view of new ground of rejection.

3. Claims 1,2,4-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleute et al. in view of Cover at al, and Parry et al, and further in view of DiGioia et al.

The instant claims are drawn to method of generating an updated surgical plan, the method comprising:

- generating a three dimensional (3D) model of a bone wherein the 3D model is based on
    1. one or more two dimensional (2D) images of the bone, and
    2. a 3D bone templates template to which a free form deformation is applied, wherein the template is chosen from a set of 3D bone templates stored in at least one storage device
- generating a surgical plan including:

    - one or more locations on the bone upon which to dispose one or more fixators, and

    - one or more settings of one or more struts of the one or more fixators, and

- based on data associated with the placement of the one or more fixators disposed on the bone, the said data being input into the computer system by means of at least one input device, generating in at least one suitably-programmed computer an updated surgical plan including updated settings for one or more of the one or more struts;
- outputting the updated surgical plan by means of at least one output device; and

- based on the updated surgical plan, adjusting at least one setting of a strut of at least one fixator

Claim 4 specifies that locations on the bone are locations for pins for fixators. Further, claims 7-10 specify that the data of locations are based on one or more images of fixators (claim 8), such as X-ray images (claim 10), which can be orthogonal to each other (claim 9)

Claim 5 specifies that settings of struts include one or more periodic adjustments of the struts

Fleute et al. teach that since the introduction of computed tomography surgical interventions are preceded by the construction of a CT-based 3D model of the object of interest to provide the surgeon with spatial information which is missing when using only 2D images. p. 138. Fleute et al. teach algorithm for generation of three dimensional model of a bone by reconstruction of 3D shapes using x-ray views and a statistical model. 3-D model of the patient bones is constructed by deforming a statistical 3-D model to the contours segmented on the x-ray views. The statistical model (template) is made of a few principal modes that are sufficient to represent the normal anatomy. Fitting the template to the segmented 2D x-ray contours of the bone is achieved by using iterative closest point algorithm to non-rigid 3D/2D registration. See Abstract and pages 143-147.

Fleute does not teach using a 3D template to which a free form deformation is applied. However, the reference teaches that "[w]hen dealing with pathological shape deformations which are not covered by the statistical model, local refinements of the

model are necessary to obtain a sufficient good fit between the model and the projective data." (p. 146).

Cover teaches use of 3D models for surgery simulation, such as interactively deformable models that would provide realistic simulation. In particular, Cover teaches free form deformation technique introduced by Sedeberg and Parry (hereinafter and in instant specification addressed as "Parry")[1]. In turn, the reference of Sedeberg and Parry et al. teaches deforming solid geometric models in a free-form manner (see p. 151), and utilizes computational method used in the instant invention as well - compare equation (2) in Parry, p. 153, and equation (8) in the instant specification. It is noted that the instant specification addresses Parry stating that "Parry's FFD technique is applied to a new area of application, i.e., three-dimensional shape reconstruction from two-dimensional images, instead of to the traditional application domains of geometric modeling and animation" (paragraph [0069]); however, per claims, the free form deformation (FFD) is applied to a 3D template, and not to three-dimensional shape reconstruction from two-dimensional images as addressed in specification.

Tanaka et al (US 6692448) teach an artificial bone template selection system which includes a template data storage system in which template data representing a plurality of templates representing a plurality of artificial bones of different shapes is stored. See claim 1. The template is obtained from three-dimensional data. Col. 11, lines 30-31. Even though the database of Tanaka is intended to be used for selection of an artificial bone template suitable for a bone to be replaced, it would be obvious that

[1] It should be noted that the reference teaches shortcomings of free form deformation technique and suggests using it in combination with energy computations.

such templates can be used for selection of appropriate 3D bone template. Further, Tanaka teaches that templates can be further deformed. Col. 9, line 51.

It would be prima facie obvious to one skilled in the art at the time the invention was made to be motivated to use an appropriately selected 3D bone template, including a deformable 3D bone model for fitting of 2D x-ray contours of the bone to an appropriate template in the method of Fleute. If there is a need to refine a statistical 3D template in Fleute to reflect shape deformations which are not covered by the statistical model and thus to provide a realistic 3D simulation of a bone, one would turn for databases of existing bone templates, such as those described in Tanaka, or if further refinement reflecting individual characteristics is needed, to interactively deformable models addressed in Cover and originally described in Parry. One would expect that a flexibility in using an interactively deformable model would ensure more realistic 3D rendering of a bone, and thus, generation of a more successful surgical plan.

Further, the combination of Fleute together with Cover, Parry, and Tanaka references do not teach using 3D model of a bone to generate a particular surgical plan for bone distraction that includes such considerations as locations on the bone where to dispose fixators, or settings of struts of fixators.

DiGioia et al teach that planning of orthopedic surgery benefits from use of computer assisted planning tools comprising imaging capabilities. (See also references

discussed in Background Section of the instant application, pages 7,8). Thus, the reference teaches:

> …Once the optimal plan is developed, surgeons will be able to implement that plan accurately and precisely. Only by coupling preoperative medical images and optimized plans with accurate tools used during surgery will the full potential of these new technologies be realized.
>
> Image guided surgical navigational tools also will provide clinical researchers with a new generation of measurement devices and intraoperative sensors which will permit the quantification of current clinical practice and provide information about surgical procedures and techniques never before available during surgery. Such quantification of intra- operative variables then can be used to analyze and validate more precisely long term clinical outcomes

As disclosed in the Background section of the instant specification, with respect to bone distraction process,

> At present, the following nominal steps are performed during the bone distraction process: (1) Determine an appropriate frame size for the fixator (e.g., for the Ilizarov fixator 20); (2) Measure (e.g., from X-rays) the deformity of bone fragments (or the anticipated fragments after surgically cutting the bone) and obtain six parameters that localize one fragment relative to the other; (3) Determine (or anticipate) how the fixator frame should be mounted on the limb; (4) Input the parameters and measurements to a computer program that generates the strut lengths as a function of time required to correct the deformity; (5) Mount the fixator frame onto the bone fragments; and (6) Adjust the strut lengths on a daily basis according to the schedule generated in step (4).
>
> The steps outlined in the preceding paragraph are currently executed with minimal computerized assistance. Typically, surgeons manually gather or determine the required data (e.g., fixator frame size, bone dimensions, fixator frame mounting location and orientation, etc.) and make their decisions based on hand-drawn two-dimensional sketches or using digitized drawings obtained by tracing X-ray images.

In *KSR Int 'l v. Teleflex*, the Supreme Court, in rejecting the rigid application of the teaching, suggestion, and motivation test by the Federal Circuit, indicated that

> The principles underlying [earlier] cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.

KSR Int'l v. Teleflex Inc., 127 S. Ct. 1727, 1740 (2007).

Applying the KSR standard of obviousness to Fleute et al, DiGioia and art disclosed in the Background section, Examiner concludes that the combination of the references is an obvious use of known technique to improve similar methods. The nature of the problem to be solved, effective preparation of surgical plan for bone distraction surgery, may lead inventors to look at references relating to possible improvements, such as use of computer assisted planning tools comprising imaging capabilities comprising three-dimensional, rather than two dimensional, model of a bone. Therefore, it would have been obvious to gather or determine the required information such as fixator frame mounting location and orientation, frame size, bone dimensions, etc., make decisions based on computational method of generating 3D model of a bone, and to implement such decisions. Using the known technique of generating 3D model of a bone to provide necessary information for preoperative planning of bone distraction surgery and then implementing such planning would have been obvious to one of ordinary skill.

With respect to dependent claims 4-6,11-13 , if there are any differences between Applicant's claimed method and that of the prior art, the differences would be appear minor in nature. Although the prior art do not teach the various details of plan development and evolution, it would be conventional and within the skill of the art to select and/or determine all necessary conditions for the intended purpose of quality planning of successful bone distraction procedure and selection of appropriate conditions for fixator frame mounting location and orientation, frame size, bone

dimensions, etc., as well as generation of surgical procedure using simulated computer animation, are conventional and within the skill in the art to which this invention pertains.

Conclusion.

4. No claims are allowed

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571)272-0720 . The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin, Ph.D./
Primary Examiner, Art Unit 1631